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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference PU0418 - PCT | FOR FURTHER ACTION See Form PCT/IPEA/416 | |
| International application No. PCT/SE2005/000467 | International filing date (day/month/year) 31-03-2005 | Priority date (day/month/year) 02-04-2004 |
| International Patent Classification (IPC) or national classification and IPC See Supplemental Box | | |
| Applicant GE HEALTHCARE BIO-SCIENCES AB et al | | |

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input checked="" type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

| | |
|---|---|
| Date of submission of the demand 05-10-2005 | Date of completion of this report 03-07-2006 |
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Form PCT/IPEA/409 (cover sheet) (April 2005)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

International patent classification (IPC)

B01D 15/10 (2006.01)

B01D 15/32 (2006.01)

B01D 15/36 (2006.01)

B01D 15/38 (2006.01)

C07K 1/16 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000467

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000467

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-------------------------|-----|
| Novelty (N) | Claims | <u>5-7, 12-28</u> | YES |
| | Claims | <u>1-4, 8-11</u> | NO |
| Inventive step (IS) | Claims | <u>5-7, 12-14</u> | YES |
| | Claims | <u>1-4, 8-11, 15-28</u> | NO |
| Industrial applicability (IA) | Claims | <u>1-28</u> | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Cited prior art:

We refer to the following document, cited in the International Search Report:

D1: US 3 869 436 A

D1 relates to the fractionating of plasma proteins by ion-exchange chromatography. The method comprises:

- precipitating the globulins in the plasma with poly(ethylene glycol) (PEG),
- centrifuging out all of the precipitate from the remaining solution,
- dissolving the precipitate in sodium acetate-acetic acid,
- adsorbing the globulins from the dissolved precipitate on a cation-exchanger,
- precipitating the eluate with PEG,
- dissolving the precipitate in phosphate buffer, and
- adsorbing the globulins from the dissolved precipitate on an anion-exchanger.

Novelty:

The method according to claims 1-4, 8 and 10-11 lacks novelty in view of D1.

The method according to claims 5-6 and 12-14 includes an affinity chromatography step and the method according to claim 7 comprises three steps. The process disclosed in D1, on the other hand, comprises two ion-exchange steps.

The method according to claims 5-7 and 12-14 is thus novel in view of D1.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **BOX V**

In the International search report, D1 was not considered relevant regarding novelty or inventive step with respect to claim 9. However, this opinion has been reassessed.

According to claim 9, the polyether is present in at least two steps. It appears from D1 (col. 3, line 7 - col. 4, line 32) that PEG is present in both the cation exchange step and in the anion exchange step. Thus, claim 9 lacks novelty in view of D1 as well.

Inventive step:

It is not considered obvious to a person skilled in the art to modify the process disclosed in D1 so as to arrive at the invention claimed in claims 5-7 or 12-14. Said claims thus present an inventive step.

The features of claims 15-17, regarding the design of the ion-exchange matrix, are known per se. They are considered to be merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Therefore, the invention according to claims 15-17 is considered to lack an inventive step.

The invention according to the independent claims 20 and 25 relates to a method for isolating an antibody compound from a liquid, comprising contacting the liquid, in the presence of a non-ionic polyether, with an ion-exchange chromatography matrix.

The method according to claim 20 differs from the subject matter of D1 in that the conductivity is specified to equivalent to 200 mM NaAc. NaAc is mentioned in D1 but the conductivity is not specified. However, this difference is not considered inventive. Thus, claim 20 and the dependent claims 21-24 lack an inventive step.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: BOX V

In independent claim 25, the design of the ion-exchange matrix is specified. For the same reasons as set out above, in connection with claims 15-17, the subject matter of claims 25-27 is considered to lack an inventive step.

Claims 18-19 and 28 relate to kits with separate compartments intended for antibody isolation. Such kits are well-known to a person skilled in the art and this solution has already been applied for the same purpose in similar contexts. Therefore, the subject matter of claims 18-19 and 28 is not considered inventive.

Industrial applicability:

The claimed invention is considered to be industrially applicable.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000467

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

In claims 7-9, it seems that the words "according to any one of the preceding steps" should be replaced by "according to any one of the preceding claims".